#### CERTIFICATE OF MAILING BY "EXPRESS MAIL"

Express Mail Label No: EL719395220US

Date of Deposit: January 15, 2002

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. § 1.10 on the date indicated above and is addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.

Rhea Amid

### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of:

Gregory R. MUNDY et al.

Serial No.:

To be assigned

Continuation of Serial No. 09/361,775

Filing Date:

Herewith

For:

INHIBITORS OF PROTEASOMAL

ACTIVITY FOR STIMULATING HAIR

**GROWTH** 

Examiner: To be assigned

Group Art Unit: To be assigned

#### PRELIMINARY AMENDMENT

Assistant Commissioner for Patents Washington, D.C. 20231

Dear Sir:

Preliminary to the examination of the above-captioned application, please amend the application as follows.

### IN THE SPECIFICATION:

At page 1, after the title, lines 4-5, please replace the first paragraph with the following new paragraph:

--This application is a continuation of U.S. Serial No. 09/361,775, filed 27 July 1999, now pending, which is a continuation-in-part of U.S. Serial No. 09/113,947, filed 10 July 1998, now pending. --

## **IN THE CLAIMS:**

Please cancel claims 3-6 without any prejudice and disclaimer.

Please replace claims 1-2 with the following clean set of amended claims 1-2. A mark-up version of the amended claims 1-2 is attached hereto as Exhibit A.

- 1. (Amended) A method to treat a mammalian subject for a condition benefited by stimulating hair growth which method comprises administering to said mammalian subject in need of such treatment an effective amount of a peptidyl aldehyde or a peptidyl epoxy ketone.
- 2. (Amended) The method of claim 1, wherein said compound is MG-132, MG-115, or MG-101 (calpain inhibitor 1).

Please add new claims 7-14 as follows:

- 7. (New) The method of claim 1, wherein said subject is a human.
- 8. (New) The method of claim 1, wherein said condition to be treated is selected from the group consisting of male pattern baldness, alopecia caused by chemotherapy, hair thinning due to aging, and genetic disorders.
  - 9. (New) The method of claim 1, wherein said subject is a non-human mammal.

- 10. (New) The method of claim 9, wherein said hair growth provides additional protection from cold temperatures.
- 11. (New) The method of claim 1, wherein said hair growth is due to thickened hair sheath diameter, increased hair diameter, differentiation of quiescent hair follicles into more mature forms, increased rate of growth in hair length and/or thickness, or the appearance of proliferation of new hair follicles.
- 12. (New) The method of claim 1, wherein said compound is co-administered with an agent promoting skin tissue growth or infiltration.
- 13. (New) The method of claim 12, wherein said agent is selected from the group consisting of an epidermal growth factor, a fibroblast growth factor, a platelet-derived growth factor, a transforming growth factor, a parathyroid hormone, a leukemia inhibitory factor, and an insulin-like growth factor.
  - 14. (New) The method of claim 1, wherein said peptidyl epoxy ketone is EST.

#### **REMARKS**

Upon entry of the present Preliminary Amendment, claims 1-2 and 7-14 will be pending. New claims 7-14 have been added. Support for the amended and new claims can be found throughout the application and *inter alia*, as follows: claim 1: original claim 3 and page 15, line 9; claim 2: page 13, lines 18-20; claim 7: page 4, line 16; claim 8: page 4, lines 22-26; claim 9: page 4, line 17; claim 10: page 4, lines 17-21; claim 11: page 4, lines 10-15, page 17, lines 1-2,

and page 18, lines 1-2; claim 12: page 6, lines 5-6; claim 13: page 6, lines 6-10; and claim 14: page 15, line 9. No new matter has been introduced by the present amendments.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing 432722002601. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: January 15, 2002

Respectfully submitted,

Peng Chen

Registration No. 43,543

Morrison & Foerster LLP

3811 Valley Centre Drive, # 500

San Diego, CA 92130-2332 Telephone: (858) 720-5117

Facsimile: (858) 720-5125

# EXHIBIT A. VERSION WITH MARKINGS TO SHOW CHANGES MADE

- 1. (Amended) A method to treat a mammalian subject for a condition benefited by stimulating hair growth which method comprises administering to said mammalian subject in need of such treatment an effective amount of [a compound that inhibits the activity of NF-κB or that inhibits proteasomal activity or that inhibits production of these proteins] a peptidyl aldehyde or a peptidyl epoxy ketone.
- 2. (Amended) The method of claim 1, wherein said compound [inhibits proteasomal activity or that inhibits production of proteasome proteins] is MG-132, MG-115, or MG-101 (calpain inhibitor 1).